K123683

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Aerocrine

NIOX® Panel – Special 510(k) SUMMARY

Doc ID: RFD-000197-00
Date Summary was Prepared: November 19, 2012

This Special 510(k) application is for the following product: NIOX® Panel as an optional accessory allowing an additional display for the NIOX MINO® Airway Inflammation Monitor.

Predicate Device:	NIOX MINO® Airway Inflammation Monitor
510(k) Clearance Number:	K101034
510(k) Holder/Submitter:	Aerocrine AB Sundbybergsvägen 9 SE-17173 Solna, Sweden Phone: +46-8-629-0780 Fax: +46-8-629-0781
Contact Person:	Kathleen Rickard, MD
Regulation Name:	Breath Nitric Oxide Test System
Regulatory Class:	Class II
Product Code:	MXA
CFR Section:	21 CFR 862.3080

Device Description

NIOX MINO is a small, hand-held, portable system for the non-invasive, online, quantitative measurement of fractional nitric oxide (NO) concentration in expired human breath (FeNO) measured in parts per billion (ppb). The device is intended for routine clinical use and laboratory assessments of the patient's condition.

Measurement of changes in FeNO concentration is used in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. All results are to be interpreted in conjunction with other clinical and laboratory assessments of the patient's condition.

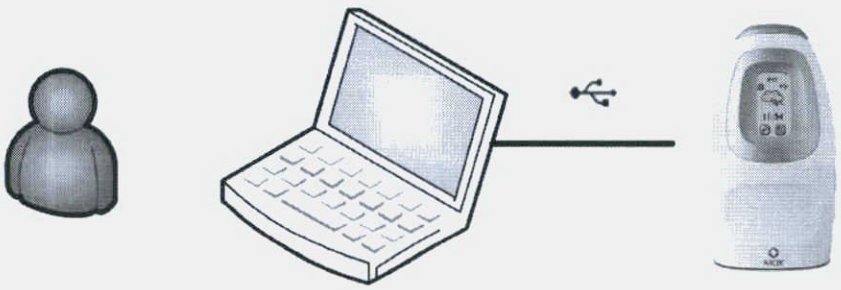
The NIOX MINO unit includes a sampling and gas conditioning system. The valves and pumps of the instrument are automatically controlled to handle the inhaled sample appropriately via the instrument electronics and software program. Filtering of inhaled air eliminates contamination from ambient NO levels. A built-in flow control keeps exhalation standardized at 50 ml/s.

Results are processed using dedicated software and are expressed as the NO concentration in ppb. In order to verify the device's performance and reliability of measurements, there are built-in system control procedures and a special designed External Quality Test Program to be performed on a daily basis.

NIOX Panel is an optional software program accessory which provides an additional display (see Figure 1) for operating the NIOX MINO Airway Inflammation Monitor by allowing the user to operate the instrument from their personal computer (PC) (see Figure 2). Interaction with the NIOX Panel is performed with common human interface devices such as keyboards, mice, etc. A USB interface is used for communication with connected NIOX MINO instruments. Instrument supervision and measurement analysis is still performed by the NIOX MINO instrument, however. The NIOX Panel merely serves as an additional interface to the instrument thus, complementing the instrument's LCD screen.

Figure 1: NIOX Panel Application Window

Figure 2: Human Interface with NIOX MINO Airway Inflammation Monitor



Intended Use

The Intended Use for NIOX MINO when used with NIOX Panel remains unchanged:

NIOX MINO® measures Nitric Oxide (NO) in human breath. Nitric Oxide is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath (FeNO), can be measured by NIOX MINO according to guidelines for NO measurement established by the American Thoracic Society.

Measurement of FeNO by NIOX MINO is a quantitative, non-invasive, simple and safe method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FeNO levels. NIOX MINO is suitable for children approximately 7 - 17 years, and adults 18 years and older.

FeNO measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. NIOX MINO should only be used as directed in the NIOX MINO User Manual and the NIOX MINO Quality Control Test User Manual, by trained physicians, nurses, respiratory therapists and laboratory technicians. NIOX MINO cannot be used with infants or by children approximately under the age of 7, as measurement requires patient cooperation. NIOX MINO should not be used in critical care, emergency care or in anaesthesiology.

Technological Characteristics

The technological characteristics remain unchanged from that of the predicate device:

1. The analytical principle of electrochemical detection remains the same.
2. The NO sensor design and signal processing remains the same.
3. The principle for sample collection and sample handling inside the instrument remains the same.
4. The format of the measurement result remains unchanged.
5. The measurement performance (precision, linearity, accuracy, detection limit) specifications remain the same.

Proposed Device Modifications

The NIOX Panel software offers the user the option of an alternative interface with a PC for interacting with the NIOX MINO device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 27, 2012

Dr. Kathleen Rickard
Aerocrine AB
Sundbybergsvagen 9
SE-17173 Solna, Sweden

Re: k123683
Trade/Device Name: NIOX MINO Airway Inflammation Monitor
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath Nitric Oxide test system
Regulatory Class: II
Product Code: MXA
Dated: November 29, 2012
Received: November 30, 2012

Dear Dr. Rickard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano

For: Courtney H. Lias, Ph.D
Director, Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123683

Device Name: NIOX® Panel as an optional software accessory allowing an additional display for the NIOX MINO® Airway Inflammation Monitor

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Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123683